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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,888	10/19/2004	Dirk Cremer	83518	4210

22242 7590 07/01/2008
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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
07/01/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,888	CREMER ET AL.	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 15-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 15-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/09/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner acknowledges receipt of preliminary amendment filed 10/19/04 and supplemental preliminary amendment filed 5/26/05 and IDS filed 12/09/05. Claims 13 and 14 are canceled, new claims 15-18 are added. Claims 1-12 and 15-18 are pending.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 5 and 15-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 5 recites the broad recitation a) fractionated fat, free fatty acids, vitamins, amino acids, branched and non-proteinogenic amino

acids, amino acid derivatives, polyphenolic compounds, isoflavonoids, carotinoids, roughage, physiologically active proteins and glycolipids, and the claim also recites specific agents of the preceding using the language of "in particular" and "such as" to define the agents/materials that are the particular fatty acids , amino acids, etc which is the narrower statement of the range/limitation.

Regarding claim 5, the phrases "such as" and "in particular" render the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

The boundaries for the protection sought by the applicant for A) derivatives of tocopherol, B) derivatives of tocotrienols, C) derivatives of polycosanols is not discernible making the claims unclear, it is unclear what the meets and bounds are for the derivatives of tocopherol, tocotrienols, and polycosanols.

It is unclear what it means to "cop with mental/ and/or physical stress and functional capacity" in claim 15.

Correction is respectfully requested.

NB: It appears that "cop" in claim 15 may be a misspelling for ---cope---, in either case, correction is respectfully requested.

4. Claims 6-11 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 6 requires the matrix of claim 1 to have a water containing coat and it is unclear if the coat is contained in the matrix or if the coat is coating the matrix and it is how clear how the matrix can have a coat.

Clarification is respectfully requested.

6. Claims 8-10 are confusing because it appears that the material of the composition of the coat is selected from, a) gelatin, … polysaccharide and mixtures thereof (claim 8), b) sugar alcohol, carrageenan, alginate, and pectin (claim 9), and c) silicon dioxide, … and talcum (claim 10) --- thus it appears that Markush language was intended for the recitation.

Clarification is respectfully requested.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-5 and 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Kiliaan et al. (WO 0184961).

9. Kiliaan discloses a capsule containing phospholipid comprised of phosphatidyl serine and phosphatidyl choline; the composition also contains DHA and EPA omega fatty acids, vitamin, coenzyme Q10, folic acid as described in Example 1; the composition meeting the limitations of claims 1-5 in the sense that phosphatidyl choline at 15.6% and phosphatidyl serine 14.4% and 15.1% of the composition is the omega fatty acids meeting the percent limitation in claims 2-4;

the DHA and EPA meeting claim 5. The composition of Kiliaan is administered to treat vascular disorders meeting claims 15-17.

10. Claims 1-5 and 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Valle et al. (WO 92/11294).

11. Valle discloses a pill or capsule composition containing phosphatidyl choline and phosphatidyl serine at 45.5% w/w, 28% w/w lactose, 5.7% w/w microcrystalline cellulose, talc and colloidal silica (page 36, example 2.1), which meets claims 1-5. keeping in mind that the composition of claim 4 contains is 10-70% or 3-20% or 1-30% or 1-5% of the designated ingredients and the fat in Valle is 45.5%. The composition of Valle is administered to treat arterial and venous thrombosis (page 1, lines27 and 28) meeting claims 15-17 deriving from the inherent properties of the phosphatidyl choline and phosphatidyl serine.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 1 and 6-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morrison et al. (US 6,103,271) in view of Haynes (US 5,091,187).

Morrison describes microencapsulated bioactive agents comprising microcapsules that are coated with phosphatidyl choline (lecithin) and phosphatidyl serine (Table VII), polysaccharides such as carrageenan (column 12, lines 12-18) meeting claims 1, 8 and 9.

Haynes discloses numerous examples of drugs that are coated with wax or lipid materials (column 5, lines 41-43), also describes injectable phospholipid coated microcrystal having particles in the range of 0.05 to 10 μm (50 nm to 10,000 nm); phosphatidyl serine can be mixed with lecithin which is phosphatidyl choline (column 14, lines 8-67). The phospholipids meet claim 1. Haynes teaches homogenizing the phosphilipid in water to produce vesicles consisting of bi-layers. Morrison does not teach that the microcapsules have water containing coat. But Haynes suggests that the phospholipids can be homogenized in presence of water. Therefore, taking general teachings of the prior art, one having ordinary skill in the art would have reasonable expectation of success by homogenizing the phospholipid with an attendant effect of the presence of water in the coat. Regarding the size of the matrix, in the absence of unexpected results, a size of 0.3 nm to 20 nm is not inventive over one of 50 nm considering that the range recited indicates that the particle size is variable.

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 1-5 and 15-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of copending Application No. 10/511884. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application uses composition comprising phoshatidtyl choline and phosphatidyl serine to effect body functions which anticipated the examined claims that use composition comprising phosphatidyl choline and phosphatidyl serine to effect body functions. The "use" language in the copending claims is taken to mean the results achieved by the application of the composition.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Priority

Please note that the priority document DE 102 50 727.9 filed 10/31/2002 is not in the application file.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/
Examiner, Art Unit 1618